



NOV - 2 2006

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Device Name: Oscera7™ Synthetic Absorbable Bone Wax
Device Model Number: OS31
Classification Name: Bone Wax (MTJ)
Device Classification: Unclassified
Predicate Devices: CP Medical Bone Wax, K024372
 Ethicon Bone Wax, (Pre-amendment)
 Orthostat Bone Putty, K043260
 Autosuture Bone Wax, K971680

Manufacturer: CP Medical
 803 NE 25th Ave.
 Portland, OR 97232 USA

**Establishment
 Registration Number:** 3032563

Official Contact: Betsy Cortelloni
 Regulatory Affairs Manager
 Theragenics Corporation®
 5203 Bristol Industrial Way
 Buford, GA 30518
 Phone: 770-271-0233
 Fax: 770-831-4369

Intended Use: The Oscera7™ Synthetic Absorbable Bone Wax is indicated in the control of bleeding from cut or damaged bones by acting as a pressure tamponade, or mechanical barrier .

Device Description: The Oscera7™ Synthetic Absorbable Bone Wax is a kneadable, biocompatible, synthetic absorbable material indicated for control of bleeding from bone surfaces. Hemostasis is accomplished by the physical mechanism of tamponade as it is pressed into the pores of the cut or damaged bone surface.

Post-application, the component materials, which include a fatty acid salt, isopropyl hexadecanoate, an alkylene oxide copolymer and β -tricalcium phosphate, are dispersed and absorbed within the body.

Substantial Equivalence Comparison: Oscera7™ has the same intended use – control of bleeding – as each of the predicates listed. Oscera7™ is absorbable, as

are the Orthostat and Autosuture bone waxes. All of the materials used in the Oscera7™ formulation have been used individually in the predicate products.

Design Verification: Verification testing of Oscera7™ included both bench and animal testing. The testing demonstrated the hemostatic capability, bioresorbability, and biocompatibility, thereby establishing compliance to the functional requirements of the device.

Conclusion: The results of verification testing confirmed that design inputs were achieved and the cumulative test results demonstrated the functionality, safety and effectiveness of Oscera7™, as well as its substantial equivalence to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CP Medical
% Theragenics Corporation
Ms. Betsy Cortelloni
Regulatory Affairs Manager
5203 Bristol Industrial Way
Buford, Georgia 30518

NOV - 2 2006

Re: K060987

Trade/Device Name: Oscera7™ Synthetic Absorbable Bone Wax

Product Code: MTJ

Dated: September 20, 2006

Received: September 21, 2006

Dear Ms. Cortelloni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

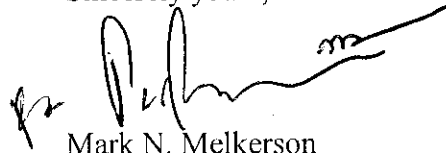
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

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marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

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510(K) number (if known): K060987

Device Name: Oscera7™ Synthetic Absorbable Bone Wax

Indications for Use:

The Oscera7™ Synthetic Absorbable Bone Wax is indicated in the control of bleeding from cut or damaged bones by acting as a pressure tamponade, or mechanical barrier.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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